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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|----------------|----------------------|-------------------------|-----------------|
| 10/717,868 | 11/19/2003 | Ingo Konetzki | 1/1428 | 9343 |
| 28501 7: | 590 09/26/2006 | | EXAMINER | |
| MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD | | | SEAMAN, D MARGARET M | |
| | | | ART UNIT | PAPER NUMBER |
| P. O. BOX 368 | • | 1625 | | |
| RIDGEFIELD, | CT 06877-0368 | | DATE MAILED: 09/26/2006 | 5 |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | ····· | | | |
|--|---|--|---|---------------------------|--|--|--|
| Office Action Summary | | 10/717,868 | KONETZKI ET AI | KONETZKI ET AL. Art Unit | | | |
| | | Examiner | Art Unit | | | | |
| | | D. Margaret Seaman | 1625 | | | | |
| Period fo | The MAILING DATE of this communica or Reply | tion appears on the cover she | eet with the correspondence a | ddress | | | |
| WHIC - Exte after - If NO - Failu Any | ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAIL nsions of time may be available under the provisions of 3 SIX (6) MONTHS from the mailing date of this communic or period for reply is specified above, the maximum statutor to reply within the set or extended period for reply will, reply received by the Office later than three months after ed patent term adjustment. See 37 CFR 1.704(b). | LING DATE OF THIS COMM 7 CFR 1.136(a). In no event, however, a lation. ry period will apply and will expire SIX (6 by statute, cause the application to become | IUNICATION. may a reply be timely filed by MONTHS from the mailing date of this come ABANDONED (35 U.S.C. § 133). | ŕ | | | |
| Status | | | | | | | |
| 1) | Responsive to communication(s) filed of | n <u>11 August 2</u> 006. | | | | | |
| 2a)⊠ | | ☐ This action is non-final. | | | | | |
| 3) | Since this application is in condition for | allowance except for formal | matters, prosecution as to the | e merits is | | | |
| | closed in accordance with the practice | under <i>Ex parte Quayl</i> e, 1935 | 5 C.D. 11, 453 O.G. 213. | | | | |
| Disposit | on of Claims | | | | | | |
| 4)⊠ | ☑ Claim(s) <u>1-15</u> is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)□ | Claim(s) is/are allowed. | | | | | | |
| 6)⊠ | ☑ Claim(s) <u>1-15</u> is/are rejected. | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | |
| 8)[| Claim(s) are subject to restriction | n and/or election requiremen | t. | | | | |
| Applicat | on Papers | | | | | | |
| 9) | The specification is objected to by the E | xaminer. | | | | | |
| | The drawing(s) filed on is/are: a) | | ed to by the Examiner. | | | | |
| | Applicant may not request that any objection | n to the drawing(s) be held in al | peyance. See 37 CFR 1.85(a). | | | | |
| | Replacement drawing sheet(s) including the | correction is required if the dra | awing(s) is objected to. See 37 C | FR 1.121(d). | | | |
| 11) | The oath or declaration is objected to by | the Examiner. Note the atta | ached Office Action or form P | TO-152. | | | |
| Priority ι | ınder 35 U.S.C. § 119 | | | | | | |
| - | Acknowledgment is made of a claim for All b) Some * c) None of: | | | | | | |
| | 1. Certified copies of the priority doc | | | | | | |
| | 2. Certified copies of the priority do3. Copies of the certified copies of t | | ···. —— | l Stogo | | | |
| | application from the International | , - | | Stage | | | |
| * 5 | See the attached detailed Office action for | | | | | | |
| | | | | | | | |
| Attachmen | t(s) | | | | | | |
| | e of References Cited (PTO-892) | | view Summary (PTO-413) | | | | |
| | e of Draftsperson's Patent Drawing Review (PTO- nation Disclosure Statement(s) (PTO/SB/08) | | er No(s)/Mail Date ce of Informal Patent Application | | | | |
| | r No(s)/Mail Date | 6) Othe | | | | | |

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DETAILED ACTION

This application was filed 11/19/2003 and claims benefit of Provisional Application 60/446,668 (2/11/2003) which claims benefit of Germany 102 56 080 (11/29/2002). Claims 1-15 are before the Examiner.

Claim Rejections - 35 USC § 112

1. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, is withdrawn due to applicant's amendments to the claim.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 1. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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2. Claims 1-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/45703 and WO 00/75114, for reasons of record.

Applicant has sent in an affidavit on 8/11/2006 showing that the activity of the combination of compounds of 2′ and 1 is more than just additive and therefore, the 103 rejection should be withdrawn in light of unexpected results. However, there is no statistical analysis of the numbers presented in the annex 2, i.e. the standard deviation of the numbers presented in the table. Further, no explanation is given for the second set of numbers in the A, B and D columns. Due to this, no correlation between the affidavit given and unexpected results can be given and the rejection is upheld.

Conclusion

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and

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any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Margaret Seaman whose telephone number is 571-272-0694. The examiner can normally be reached on 730am-4pm, Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000/

Primary Examiner
Art Unit 1625

dms